

Comments on Human Health Data Elements

12/01/15

Subgroup	Data Element	Description	Additional Comments
Contact Information	Submitter Name	Name and title of the individual submitting the incident report to the EPA.	<p>It is essential to have way to verify and validate the entry for follow-up.</p> <p>With potential threats related to job-loss, anonymous reports should be allowed. If the data will be covered under HIPAA, anonymous reports may be preferred.</p> <p>Agree that we need an option that protects the identity of submitter.</p> <p>I concur with the suggestion to make this an optional element.</p> <p>This would be valuable information for follow up opportunities should they be needed but not required.</p>
	Submitter Organization	For 6(a)(2) reporting, the name of the registrant submitting the incident report. For other reporting, name of the entity (e.g., government agency, nonprofit organization, or academic institution) that is submitting the incident report to the EPA. If it is a private citizen, enter "private citizen."	
	Submitter Category	Category of the entity submitting the report. ("Registrant" for 6(a)(2) reports)	Consider changing this to a binomial (yes/no) question: Do you represent a pesticide registrant?
	Submitter Address	Address of the individual reporting the incident to the Registrant or Registrant Agent.	Address might end up being limited to state but as much information on region as possible is useful for looking at trends. The caution on contact information needs to be balanced with utility as much as possible.

	Submitter Phone Number	Phone number of the individual reporting the incident to the Registrant or Registrant Agent.	<p>For an ideal research purpose one form of follow-up phone or email (or address) is essential.</p> <p>If these data will not be used to initiate enforcement, there's no need for PII, and it can be extremely problematic (once collected).</p>
	Submitter Email	Email of the individual reporting the incident to the Registrant or Registrant Agent.	<p>For an ideal research purpose one form of follow-up phone or email (or address) is essential.</p> <p>Make it optional, and clearly explain how it may be used. It won't be shared with other entities. It will be used to send you a receipt (or confirmation) after filing your report.</p>
	Report Date	Date that the incident report was prepared.	Preparation date not very valuable.
	Contact Name	Contact information for a person, other than the submitter, who may be contacted for obtaining further information on the incident. This may be the complainant, a physician, a veterinarian, or a wildlife biologist.	<p>It is essential to have way to verify and validate the entry for follow-up; I agree, the dangers outweigh the risks (mentioned earlier).</p> <p>There are two costs:</p> <ul style="list-style-type: none"> - Some will abandon the process if asked for PII, even if it's optional. - It makes the form longer. <p>The dangers outweigh the risks. There are two costs: some will abandon the process if asked for PII, even if it's optional; It makes the form longer</p> <p>Under 2. – do you mean PII?</p> <p>Should there be missing elements in the initial report, it would be necessary to be able to contact this person for more details. Should this information not be available following up on the incident may be impossible.</p>
Incident Data	Incident Type	Human.	If there's only one option in this system, don't bother the user with it. All incidents submitted using the 'human' system could be automatically assigned this incident type.
	Reporter's Case Number	Non-OPP case number from submitter for the incident (if exists).	Should be optional since it won't always exist
	Incident Location	The location where the pesticide exposure is believed to have occurred. Location fields will include Town/City, County/Province, State, and Country.	<p>As much as possible</p> <p>Keep it simple – I would suggest 3 text fields for location: County, State, and Other (for international or unknown)</p> <p>Essential for states to determine who the responsible party may be that was involved in the incident.</p>

	GPS Coordinates	Latitude and longitude coordinate of the incident location.	optional but collect if available Nice, but not essential.
	Exposure Date (Start)	Date of the exposure, or if more than one day, the start date of the exposure.	I think asking for 5 dates is a bad idea. It's difficult for laypersons to assess the end-date for exposure, and I think the exposure scenario is best described in narrative form. What's the end date for permanent outcomes? What if some symptoms resolve quickly, and others linger? Again, a narrative is best for exposure scenarios. Professionals will trudge through the form, no matter how long, but if you're hoping to garner reports from the general public, keep it simple and as short as possible. Simplified, I would ask for the date the exposure began, and that's it. This may be very difficult for farmworkers to ascertain. Confusing. Exposure vs. incident date
	Exposure Date (End)	End date range of the exposure.	Should have an option to include 'ongoing' exposures Ditto
	Incident Date (Start)	Date of the observed adverse effects, or if more than one day, the start date of the observed adverse effects.	Prefer just incident data.
	Incident Date (End)	End date of the observed adverse effects.	See comments As noted, this may be difficult to determine. There may also be liability issues concerning longer term impacts. Affected individuals might feel reluctant or uncomfortable in responding. Unlikely that there will be an end date.
	Date Comment	Use to provide information about the timing of the incident when exact dates are not known. (Example: "Early April"). May also be used for comments concerning the start and end dates.	Instructions for this should be very specific. Exact dates needed. Can always be corrected to actual dates later.

	Incident Awareness Date	Date when the registrant, or registrant agent, became aware of the incident. Not applicable to non-6(a)(2) incident reporting.	Not very valuable.
	Notification (Yes/No)	Indicates if the incident was reported to a government agency other than the EPA, such as a state government office.	<p>Pesticide product labels carry 1-800-832-4357 safety call hotline for emergencies, medical and environmental reporting; can EPA tap this database directly or learn from their approaches.</p> <p>I like the way it's worded - it's clear that you're asking about reports to government entities</p> <p>Yes - NGOs</p> <p>Need date of reporting, what entity reported to and who specifically reported to if possible.</p>
	Notification (Text Field)	Identifies the federal, state, or regional government office (other than EPA) that was notified of this incident.	<p>this field is not essential to an individual entry in the database, but there is a need to avoid double and triple counting of incidents – if this field is part of that goal it becomes a 3</p> <p>Why is it useful to list all of the entities aware of this incident? If the only reason is completeness, we should be careful about adding this burden</p> <p>Since this may be multiple agencies, I recommend this being a one-to-many relational db.</p>
	Part of a Study?	Indicates if the incident part of a larger study? An example is ongoing worker exposure studies.	<p>Agreed</p> <p>More important for 6(a)(2) reports, less so for other incidents</p> <p>Delete</p>
	Status (New or Update)	Indicates if the report is for a new incident or an update to a previously submitted incident.	<p>Seems messy - How will you match up related reports? Does the user have to fill out a whole new report (all fields) just to provide an update? Will submitters of new reports infer that updates are required?</p>
Number Affected	Number Affected	The number of persons having the adverse effect. Enter the exact number.	<p>Messy without understanding how this relates to other entries</p> <p>We built such a relational database at NPIC. We find this approach to lumping/splitting useful--If a group has essentially identical exposures and signs/symptoms, they can be lumped and described as one entity. For example, a big group of office workers or a family. - If individuals have different exposures and/or signs/symptoms, they have to be entered singly.</p>

Pesticide Information	EPA Registration No.	EPA Product Registration Number. Include the 1-6 digit manufacturer number and the 1-5 digit product identification number. Separate the two numbers with a hyphen. Distributor's number, if applicable, is entered separately.	<p>Again and either or situation, if you have this you don't need other pesticide info but if you don't have it other field become essential.</p> <p>I think a missing Reg. No. can render the report useless. If the reporter cannot find it, maybe they don't have enough information to submit a formal report yet. There have been exceptions, of course, but the interface should emphasize the importance of the Reg. No. Without it, the report cannot be attributed to any specific product, but it could still be useful for overall risk/incident estimates.</p> <p>Useful if we can get it</p> <p>Many pesticide applications include multiple pesticides and adjuvants so the database needs to allow collection of information for multiple products.</p>
	Batch Number	The batch number that is printed on the label of the product that was applied in the incident. Record for each product associated with the incident.	<p>I have been working with pesticides for a decade, and I don't know how to find the batch number on pesticide product labels. I think the cost (frustration) is higher than the potential benefit.</p> <p>Not very valuable.</p>
	Canadian Reg. No.	Canadian product registration number (for Canadian incidents only)	<p>I think it makes sense to narrow the scope to EPA-registered products or 25(b) exempt products. Canada has a similar system already online.</p> <p>Not very likely to have Canada number.</p>
	Product Name	Product name. Should include the complete trade name, including codes describing the formulation, and any description of pesticide type. Example: "Propazine 80W Herbicide"	<p>Could get from reg no above.</p> <p>Agreed - it has to be relational. It gets worse... sometimes there are multiple people and they weren't all exposed to the same product(s), but share some of the same exposures</p> <p>As specific info as is possible for the reporter to report.</p>
	Product Formulation	Formulation type of the product as purchased.	<p>Can obtain this and information in the following fields (through RUP) if the EPA Reg No is known. This could be information that would "self-populate" if the system is connected to OPPIN or a registration data base.</p> <p>If possible</p>

	Formulation as Applied	Formulation type of the product when it was applied (e.g. diluted solution, granule, dust, etc.)	<p>Huh? Could be confusing. Most of the time, it will be identical to the preceding field.</p> <p>Drop down list?</p>
	Active Ingredient	Common name of the active ingredient to which the affected person or other organism was exposed.	<p>Essential but could come from product name or reg no.</p> <p>Auto-populate would be great</p> <p>If possible</p>
	Active Ingredient Comment	Information on the identity of the active ingredient when the specific ingredient cannot be identified or is not on the drop-down list. Enter the ingredient name if known but is not on the list. If the ingredient identity is unknown, enter the known or suspected chemical class or classes (e.g., "carbamate" or "anticoagulant rodenticide") or enter "unknown."	<p>Recommend equation for this field that will pop up when, for the scenario above, "herbicide" or rodenticide" is chosen.</p> <p>Is there a separate element for "chemical class"? Do we need one?</p> <p>Not sure this info would be available.</p>
	Toxicity category	Signal word (Danger, Warning, or Caution) for acute oral toxicity class of the active ingredient.	<p>if you have product/active info, this is not essential, but could be post processing info</p> <p>Call it the signal word rather than toxicity category. Idea: If the EPA Reg. No. is provided, auto-populate the product information fields from PPIS.</p> <p>Would this field be seen by the user, or just added to our DB?</p> <p>If possible</p>
	Restricted Use Product	Indicates if the product is a restricted use product	<p>if you have product/active info, this is not essential</p> <p>If they know the Reg. No., you can find this out. If they don't, they won't know whether it's Restricted Use.</p> <p>Would this field be seen by the user, or just added to our DB?</p>
Application Information	Application Site Category	General category of application site (Agricultural, Residential, Commercial, etc.)	<p>This would be problematic to define. If used, consider adding a category "Mixed/Uncertain".</p> <p>Very general info helpful.</p>

	Worker Protection Standard	Does the person affected fall under the worker protection standard (yes/no)	<p>Would think this would be covered by other entries but not sure.</p> <p>Laypersons will not know how to answer this question. Perhaps it could be worded, "Are any of the people involved agricultural workers?" It's close to the same question, and easy.</p>
	Application Site	Description of the site where the pesticide product was applied. If it is an agricultural site, identify the crop. If an accidental exposure, enter the site of the exposure. If applied to an animal, enter "Animal treatment".	<p>As much as possible</p> <p>Maybe prompted them first: for the nature of the exposure, which would lead them to specific questions.</p>
	Application Method	Description of method used to apply the pesticide. Examples include aerial spraying, ground spraying, granular application, and bait placement.	<p>As much as possible</p> <p>Use a drop-down menu with "Other" as an option. Aerial, ground sprayer, hand-held sprayer, fogger, other. Keep it simple. Remember, there will be insect repellents, antimicrobial wipes, and impregnated materials. You can't possibly think of them all.</p> <p>Definitely one-to-many potential here</p>
	Application method specific	Description of the specific type of method used to apply the pesticide, indicating the general type of equipment used.	<p>Confusing</p> <p>Maybe relabel equipment used. One-to-many</p> <p>Not clear why this is different from Application Method, above.</p> <p>Duplicative</p>
	Application Rate	Rate of the application of product, if known. Enter value and units.	If available
	Misuse	Yes/No/Uncertain. Indicates if the manner the product was used was in violation of the label.	<p>If got all the other info, you could determine this after the reporting, not as part of the report.</p> <p>As a former SLA investigator, I can tell you this is not an easy question. What value is there, asking a layperson this question? It will be his/her opinion.</p> <p>Would some submitters be deterred by this question (and thus not respond/ give dishonest answers)? Would it help at least somewhat to turn around the question and ask if it was used "in accordance with" or "consistent with" the label rather than in violation?</p>

			A decision on whether a violation occurred may be difficult to determine early.
	Misuse Comment	For misuse cases, comment on evidence indicating misuse of the product.	In the incident.
	Applicator Certification	Yes/No. Indicates if product was applied by, or under the supervision of, a certified applicator.	If available
Incident Description	Incident Description	Description of what happened, including a general description of the suspected pesticide exposure and the adverse effects/symptoms observed. Also may include other important details not captured by the other data fields.	<p>SYMPTOMS SHOULD BE CAPTURED SEPERATELY, they are one way of validating causality linkage</p> <p>Maybe separate out adverse effects/ symptoms in to one field (one-to-many relationship), since this seems to be more specific</p>
	Incident Site	Description of the site where the person or organism was exposed to the pesticide, or if unknown, enter where symptoms, mortality, or other adverse effects were observed.	<p>Should have enough information to help confirm or dismiss causality</p> <p>Consider changing to "Exposure site." Otherwise, it's confusing because they already entered the application site.</p> <p>The previous data element sounds very similar to this one.</p> <p>Duplicative</p>
	Route of Exposure	Primary the route of exposure of individuals affected (e.g., oral, dermal, inhalation, or ocular)	<p>For a lay person this should be broken up, did you ingest it? Smell it? Spill it on you?</p> <p>Remember to allow for multiple and unknown routes.</p> <p>Should just be areas affected vs. "primary".</p>

	Exposure Pathway	The route of transport of the pesticide from the site of application to the affected organism (e.g., spray drift, run-off, volatilization, secondary exposure).	<p>Most people can't differentiate spray drift from volatilization - this could be a field used in analysis of the incident by OPP but not collected at time.</p> <p>Might change it to read, "to the affected individual" – not the affected organism.</p> <p>Seems like this info would have been collected earlier.</p>
Lab Report	Lab Report Title	Title or description of the laboratory report(s) that the submitter attaches or encloses with the incident report submitted to the EPA.	<p>Does this apply to items other than FIFRA? Bee kill lab reports? Worker comp urine tests? Does this help avoid triple counting?</p> <p>Asking for the lab report implies that the report won't be given much weight without a lab report. That's one cost, and the benefit is low. Lab reports are rarely available.</p>
	Lab Report Number	Report number for the laboratory report.	
Demographic Information	Case ID	ID used in the incident report to identify individuals affected. If none are given, sequential numbers will be assigned.	<p>post processing not part of the incident collection process</p> <p>This should be automatically assigned. I think it might be better to call them Entity IDs, or person IDs.</p>
	Age	The age of the individual exposed. Enter number and unit, or a general description (e.g., young adult)	Potential for multiple here. Definitely need relational db here.
	Sex	The sex of the individual exposed.	<p>Weight is more helpful than sex for dose assumptions</p> <p>Except for identity purposes.</p>
	Occupation	If the incident was occupationally related, state the occupation of the individual involved.	If it was occupationally related, that will be described in the narrative. If not, this question is highly off-putting.
	Suicide/homicide	Yes/No. Indicate if the incident was the result of a suicide or homicide.	<p>Rare. Problematic. If you're looking for ways to simplify, I would cull this question. It will be clear from the narrative. We have spoken with several people who assert their spouses or neighbors are trying to kill them with pesticides in some way. I worry that this question might make those individuals feel like they have submitted an official allegation of attempted murder, and this is not the forum for that kind of report.</p> <p>? Would tracking of this info be necessary?</p>
	Pregnancy Status	Pregnancy status of individual exposed.	<p>PII?</p> <p>Except for identity purposes.</p>

Exposure	Exposure Activity	Description of how the product was being used at the time of the reported incident, or what the exposed individual was doing when the exposure occurred.	<p>Seems to overlap with incident descriptions above These two fields seem repetitive, especially after the user has entered the "incident description." Consider combining these two into one. "Circumstances of Exposure."</p> <p>I'm not sure exactly what sorts of answers we're expecting here (vs. next question). Maybe give an example?</p> <p>Duplicative</p>
	Circumstances of Exposure	Description of the event that caused the pesticide exposure.	<p>Repeated data element? Seems that we went over this above, but I could be wrong.</p> <p>Duplicative</p>
	Exposure to Concentrate	Yes/No. "Yes" indicates the product is sold in a concentrated form and the incident involves exposure to the concentrate prior to dilution.	Duplicative
	Protective equipment (Yes/No)	Indicates if any personal protective equipment (PPE) was used by the affected person(s) at the time of the incident.	If needed, clarify that long pants, long sleeves, and closed-toe shoes can be considered PPE.
	Protective equipment	Description of the type of personal protective equipment (PPE) and protective clothing that was used or worn by the affected person(s) at the time of the incident.	Would be good to be as specific as possible to compare to label requirements re PPE
	Workdays lost	Number of workdays lost due to the incident, if known.	<p>Is this OSHA reportable workdays lost or just they took time off?</p> <p>How can this be verified?</p>
	Time to Symptoms	Indicate how long after the incident occurred that the first signs and symptoms were noted.	<p>WHERE is the description of the actual symptoms? Consider adding another field, "Duration of (most) Symptoms"</p> <p>Maybe merge this question with earlier ones about exposure dates and observed adverse effects?</p> <p>Duplicative</p>

Adverse Effects	Medical Care	The type of medical care or consultation sought. Examples include none, clinic, hospital emergency department, private physician, PCC (Poison Control Center), hospital inpatient.	Consider changing to Yes/No. It will be easier to compile the data as numbers. I hope this is not weighted too heavily, as often people avoid medical care for a variety of reasons. Need specific entity/location/date/time seen.
	Symptom Type	Classification of the type of symptom(s) observed. May select more than one.	Stronger description than just <i>type</i> needed This would be hard for laypersons to do. Is a headache a neurological symptom? Yes, according to RMPP. I think the symptoms comment field is appropriate and sufficient. Duplicative
	Symptoms Comment	Optional field to provide a more detailed description of the symptoms that correspond to the symptom type.	Strong emphasis on symptom description needed, BACKGROUND info on other possible causes NEEDED TOO.
	Case Outcome	Characterization of the current status or final outcome of adverse effects.	Unclear at the time of the reporting? It's arbitrary because the report may be filed in the middle of the response or years later. The data from this field won't be useful because of that variation. If we ask about duration of (most) symptoms, this field wouldn't be necessary. May be ongoing, which could be an option May be hard to determine.
Lab Results	Lab Test Results	Results of laboratory tests, such as blood test or urine analysis.	If used, consider giving an example of the desired format. For example: Positive/negative; 4.0 ppm permethrin in urine collected within 3 hours of exposure; depression of cholinesterase confirmed; One-to-many relationships
Residential (non-ag)	Indoor or Outdoor	Indicates if the product was used indoors or outdoors	
EPA Fields	PC Code	PC Code(s) of the active ingredient(s) to which the affected person or other organism was exposed.	Could be obtained from other info above

	Certainty	EPA's conclusion on the certainty that the ingredient caused or contributed significantly to causing the observed adverse effects. Entered for each ingredient.	<p>VERY IMPORTANT but not much in this database to look at alternative scenarios or illnesses to test pesticide exposure hypothesis</p> <p>Consider assigning a certainty index for each person, rather than each active ingredient. People may have wildly different symptoms.</p> <p>Should be not only EPA's determination, but also the state lead agency if reported. Many cases take a long time to resolve.</p>
	Certainty Discussion	A brief discussion of the evidence supporting the certainty level that EPA assigned to the ingredient.	Certainty about the cause, not about the ingredient... wording is awkward.
	Legality	EPA's categorization on the legality of the pesticide use. Legality categories are "Registered Use," "Suspected Misuse," "Known Misuse," and "Malicious Intent." ["Malicious Intent" used for intentional targeting of affected person or non-target organism.]	<p>This field is potentially very problematic. Investigations are needed to determine legality, with full label review and site inspection. Making this characterization casually could violate state primacy.</p> <p>Again. Asks for a conclusion that may not be able to be determined with the data collected.</p>
	Exposure-Severity Code	Code that indicates the type of incident and the severity level of the incident.	Again, this would have to be assigned for each person involved in the incident.